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Change Request 4636 – ABC3 User Guide

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Glossary of Terms:

List any new terms created in this document. Mail the NPO Quality Manager to have these included in the master glossary above [1].

Term	Acronym	Definition

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1 Introduction

NHS CSP and Royal College of Pathologists have agreed to the revision of the 'ABC' guidance and that an updated version is required.

The principal changes to the guidelines are as follows:

- a) The NHSCSP will adopt the revised BCSS terminology for reporting cervical cytology.
 - Division of the category 'borderline change' into 'squamous' and 'endocervical' categories.
 - Division of 'dyskaryosis' into 'low grade' and 'high grade' categories (the latter encompassing moderate & severe dyskaryosis).
 - Division of glandular neoplasia into 'endocervical' and 'non-cervical' categories.
- b) Guidance on the management of abnormal cytology results has been linked to the new terminology:
 - Management guidance has been updated in the light of HR-HPV testing for triage of low-grade cytological abnormality and test of cure.
 - Expanded codes have been developed for standard cytology results to take account of the changes outlined above.

The above changes require the introduction of 4 new result codes. These new result codes are as follows:

Code 0 (?Glandular neoplasia (non cervical)).

To be treated exactly the same as code 2 (negative) for cervical screening purposes. This includes result types, recall dates and statistical reports.

Code G (?Glandular neoplasia (non cervical) – HPV tested)

This is required for the same reasons that we have a code N (negative – HPV tested) to mirror code 2 (negative), and should be treated the same way i.e. as negative for result types, recall dates and statistical reports but a different result letter.

Code 9 (Borderline change in endocervical cells)

To be treated exactly the same as code 8 (borderline) for result types, recall dates and statistical reports. Result letters will be worded differently. The main difference between code 9 and code 8 is that borderline/endocervical cells should be "treated with greater caution" than borderline/squamous cells [ref. ABC2 p.12] and so it will be helpful for screening staff to know precisely which type of borderline a woman has (or has had in the past).

Code E (Borderline change in endocervical cells – HPV tested)

This code is required because code 9s are still borderline and therefore will be treated same as code 8S for HPV triage purposes. Code E will appear far more frequently than code 9, since virtually all borderline tests should be HPV-tested.

2 System Changes

The introduction of these result codes has impacted on several core areas of the current system. These areas are as follows:

- FD Screen HA Details
- DD Screen District Details
- LD Screen Laboratory Details
- Laboratory Links

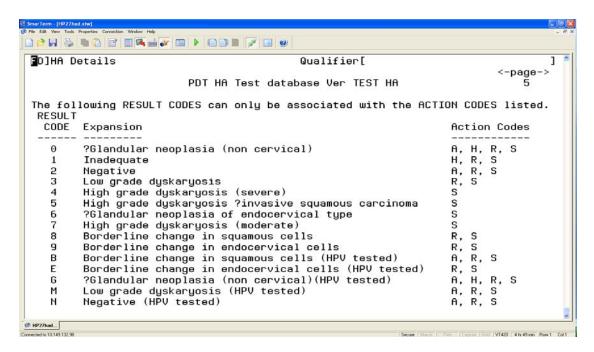
- Manual Matching Screen (MM)
- CY Screen Cytology Tests
- AJ-CIN HA-HA transfer of deducted tests/redirected tests
- AJ-CP Result Letter Print
- AJ-RP Invitations, Reminders, First/Final Non-responders etc.
- CSSE Enquiry Package (To be amended & released separately)
- HPV to Non HPV mapping routines
- KC53 Statistics (To be amended & released separately)

3 FD Screen Changes

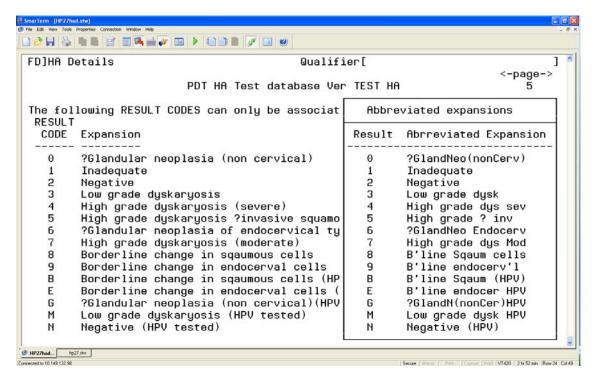
3.1 Page 5 Changes

3.1.1 Display Screen

Changes have been made to page 5 of the FD screen to include new result codes 0, 9, E and G and to change current expansions for the existing result codes 3, 4, 5, 6, 7, 8, B & M to the new expansions according to 'ABC3' guidelines.



We have introduced a pop-up window to display the abbreviated expansion for each result code. These abbreviations are used throughout the system for reports and are limited to 18 characters. This pop-up window can be accessed from the KEY field in the normal way.



3.2 Page 9 Changes

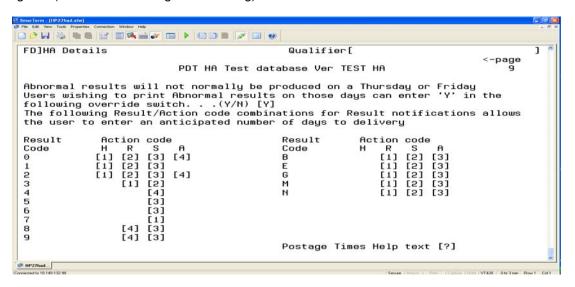
New result/action codes have been added to allow anticipated (estimated) delivery days to be set. A PSAU will be issued to set up new 'Estimated days to delivery' for the new result codes.

Action: Please note that the number of days will be set initially to 6. This is the maximum allowed so you will probably wish to alter the number of days.

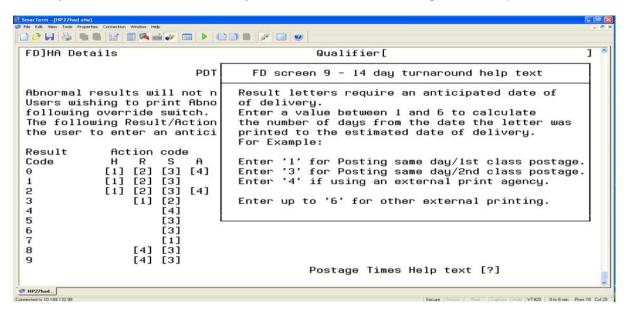
3.2.1 Display Screen

The PSAU will install the new result /action codes, pre-set to 6 days for the anticipated number of days to delivery. It is up to each PCO to reset the number of days in line with policy.

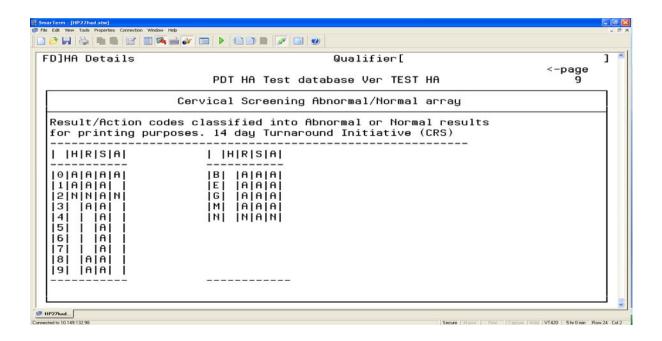
This number of days setting is required for the calculation and setting of the anticipated date of delivery of a cytology result letter. This date is used to calculate the 14 day turnaround figures (CSSVSA – vital signs monitoring).



The help text that was originally displayed on page 9 has been moved to a pop-up window. This may be accessed in the normal way from the '?' box next to Postage Times Help.



The pop-up window that is accessed via the KEY field on page 9 to display abnormal results for CP printing has also been amended to include the new result codes.



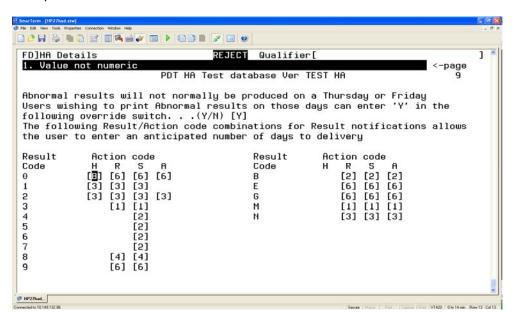
3.2.3 Page 9 Validation

Amend validation to check a numeric value in the range 1-6 is correctly entered against each new result/action code.

If a value other than 1, 2, 3, 4, 5 or 6 is entered the appropriate REJECT error message is displayed. Available error messages are:

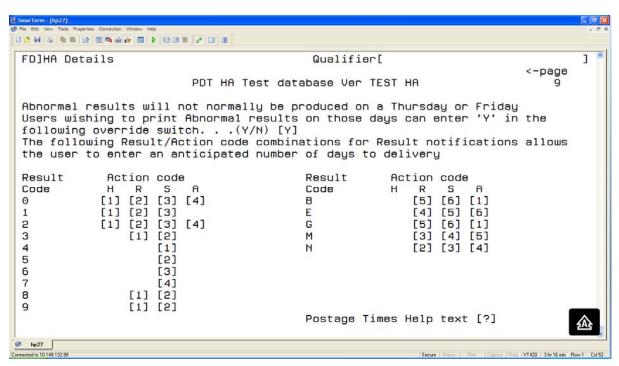
- 1. Value is greater than 6
- 2. Value not > '0'
- 3. Value not numeric

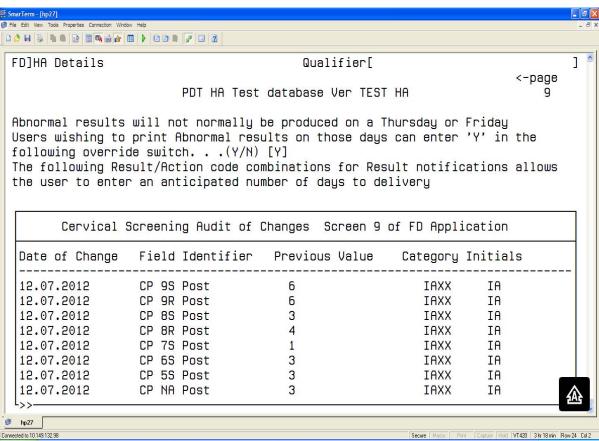
Example:



3.2.4 **Update**

New values will be updated onto the 'Anticipated no of days file. The change is captured on the FD screen audit file and may be viewed via the pop-up window. The pop-up window is accessed from the Qualifier field in the normal way.

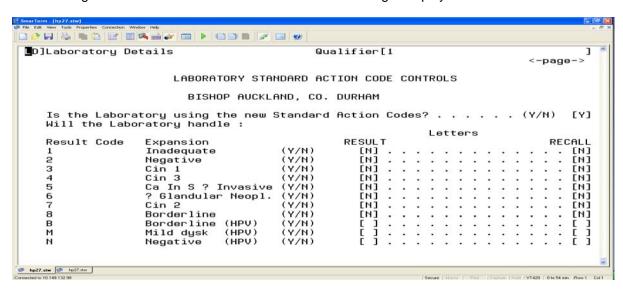




4 LD Screen - Page 3 Changes

The LD screen page 3 which controlled Laboratory result and recall notifications has been disabled. This decision was made by the CSUG as laboratories should no longer be producing result/recall notifications.

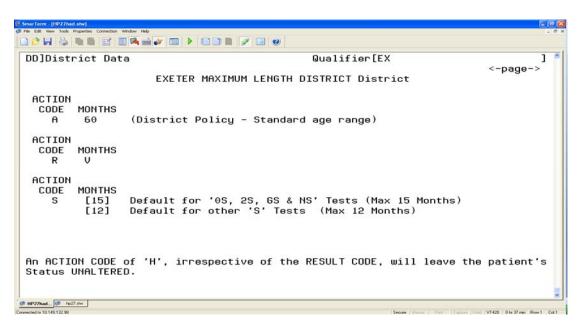
The following LD screen has now been disabled and will no longer display.



5 DD Screen Changes

5.1 Page 3 changes

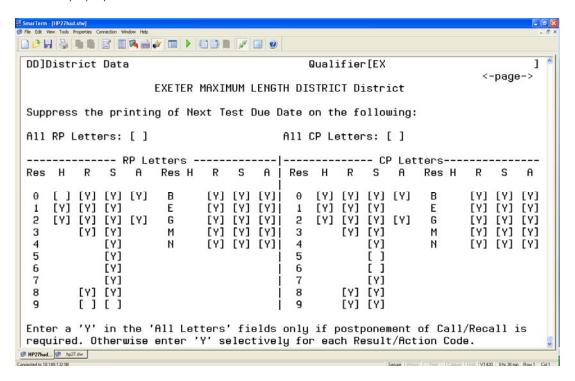
Page 3 of the DD screen has been amended to include results coded 0S, GS & NS under the maximum default of 15 months. Screen will now display as follows:



It should be noted that 'R' action coded tests where the HPV infection is classed as 'unreliable' will have a maximum repeat months of 6.

5.2 Page 6 Changes

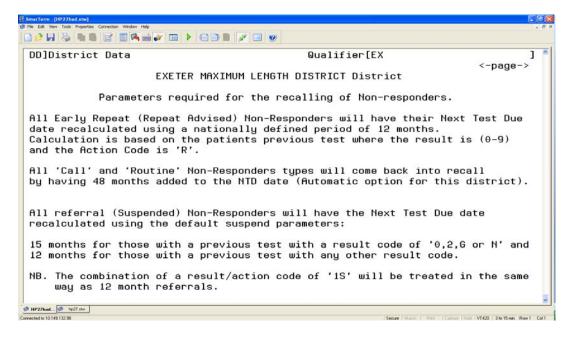
Page 6 has been amended to include the new result codes of 0 & 9 and all the HPV coded tests of B, E, G, M & N.



ACTION: Please note new fields on this screen will initially be blank, and will require setting up if your organisation uses NHAIS letters.

5.3 Page 7 Changes

Result codes 0 and G have been added to the referral text for Final Non-responders who are referrals (suspended).

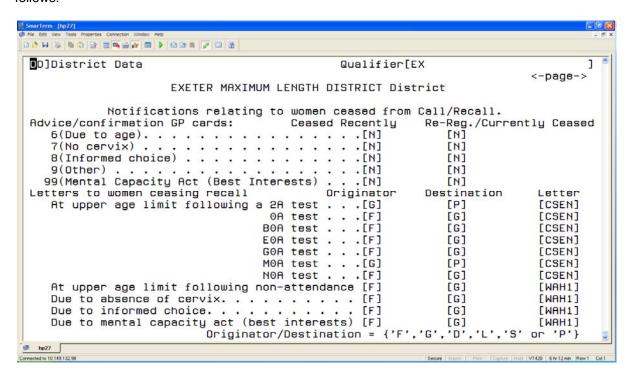


5.5 Page 8 changes

Women may now be ceased 'due to age' following any 'A' coded test result (see ceasing rules in Section 12 - Appendix A

ACTION: Please note the new ceasing letters will need to be set up on LL, DD and PEP or similar application, where used, as soon as possible. The national letter templates will be advised by NHSCSP.

DD screen page 8 has been amended to add 6 new result codes to the cease 'due to age' letter options to enable the new letter Identifiers to be entered. This screen will now display as follows:



5.6 Page 10 onwards - Changes to the Result Code/Action Code Letter pages

A PSAU will be issued to set up the new result and action code combinations on the District Details Screen.

The DD screen pages allowing for result notifications to be entered have had several new pages added. They have also had result code/action code pages removed.

New pages added are as follows:

0A, 0H, 0R and 0S
9R and 9S
E0A, E0R & E0S
E9S
Infection HPV Negative
Infection HPV Positive
Infection HPV Unreliable
G0A, G0R & G0S
Infection HPV Negative
Infection HPV Positive
Infection HPV Positive
Infection HPV Unreliable

ACTION: Please note the new result and recall letters will need to be set up on LL, DD and PEP or similar application, where used, as soon as possible. The national letter templates will be advised by NHSCSP.

We have taken the opportunity to remove the DD screen pages for result/action code combinations that are no longer valid. Combinations removed are: 4R, 5R, 6R and 7R.

Please note that even though the removed (as above) result/action code notifications screens are no longer available for viewing or amending the original data continues to be held in the background. This ensures that appropriate invitation/reminder etc will be issued when required.

We have also rationalised the screens to remove 'Infection Present', 'Infection Not Present' for result codes 1 and 2 as infection is no longer relevant for these results. The letters (codes) are the same regardless of the infection code therefore the DD screen will display only 1 screen for each action code (the 'Infection not Present) screen. Validation and update will apply only to the 'No infection' letters.

As infection now only applies to HPV tested results the DD screen will no longer display the heading 'Infection' except for those result codes (B, E, G, M & N) where infection is required.

6 Laboratory Links Changes

6.1 Validation

The laboratory links application has been changed to receive and validate the new result codes.

All result/action code combinations for the 4 new result codes will be validated against the following rules:

0 = "?Glandular Neoplasia (non cervical)"

New Result Code	Infection Code	Action Code	Repeat Months	
0	N/A	А	36 months if < 50 60 months if >49	As per District Settings
0	N/A	R	Up to 36 months maximum	
0	N/A	S	Maximum 15 months	As per District Settings
0	N/A	Н	None	

9 = "Borderline changes in endocervical cells"

New Code	Result	Infection Code	Action Code	Repeat Months	
9		N/A	R	Maximum 12 months	
9		N/A	S	Maximum 12 months	As per District Settings

G = "?Glandular Neoplasia (non cervical) HPV Tested"

New Result Code	Infection Code	Action Code	Repeat Months	
G	0	А	36 months if < 50 60 months if >49	As per District Settings
G	0	R	Up to maximum of 36 months if < 50 OR up to 60 months if >49	
G	U	R	Up to 6 months maximum	
G	0	S	Maximum 15 months	As per District Settings

G	9	S	Maximum 15 months	As per District Settings
G	U	S	Maximum 15 months	As per District Settings

E = "Borderline changes in endocervical cells (HPV tested)"

New Result Code	Infection Code	Action Code	Repeat Months	
E	0	Α	36 months if < 50 60 months if >49	As per District Settings
E	0	R	36 months if < 50 60 months if >49	
E	U	R	Maximum 6 months	
E	0	S	Maximum 12 months	As per District Setting
E	9	S	Maximum 12 months	As per District Setting
E	U	S	Maximum 12 months	As per District Setting

Any test result that fails validation will be rejected. The rejected test will be reported on the Laboratory Links Error report and a residual card will also be printed.

In addition to the introduction of the new result codes we have amended the validation to REJECT Result/Infection/Action code combinations of B9R, M9R and N9R as these are no longer valid. Although these results will be rejected by the Lab Links software, they will continue to be considered valid when entered via the CY screen. This is to enable historic tests to be entered when required.

Test results that have an action code of "A" (0A, 2A, B0A, E0A, G0A, M0A & N0A) will also be validated against the new 'ABC guidelines' for 'return to routine recall'. These guideline changes are explained in Section 12 of this document.

A woman may also be ceased automatically 'due to age' when an 'A' coded test is entered if her recall date is after her 65th birthday subject to ceasing rules checks. These checks are explained in Section 11 of this document.

6.2 Print Routines

Two new error messages have been introduced and will appear on the Laboratory Links Matching/Error reports and the Residual Cards. They are:

"Infection code must be 0 or U for this result/action code. Contact the Laboratory." (This message will apply to any test coded BR, ER, GR, MR or NR that has an infection code 9. The infection code must be present and can only be 0 or U)

"Repeat months exceeds maximum allowed for this result/action code. Contact the Laboratory"

7 CY Screen Changes

7.1 Validation

Changes required to the validation routine to enable the entry of the following new result codes.

0 = "?Glandular Neoplasia (non cervical)"

New Result Code	Infection Code	Action Code	Repeat Months	
0	1-7 If present	A	36 months if < 50 60 months if >49	As per District Settings
0	1-7 If present	R	Up to maximum of 36 months	
0	1-7 If present	S	Maximum 15 months	As per District Settings
0	1-7 If present	Н	None	

Although infection may be present for Result Code 0 it can be disregarded and not recorded as the result letter does not need to be infection specific.

9 = "Borderline changes in endocervical cells"

New Result	Infection	Action	Repeat Months	
Code	Code	Code		
9	1-7	R	Maximum 12 months	
	If present			
9	1-7	S	Maximum 12 months	As per District Settings
	If present			•

As per Result code 0 - although infection may be present for Result Code 9 it can be disregarded and not recorded as the result letter does not need to be infection specific.

G = "?Glandular Neoplasia (non cervical) HPV Tested"

New Code	Result	Infection Code	Action Code	Repeat Months	
G		0	Α	36 months if < 50 60 months if >49	As per District Settings
G		0	R	Up to maximum of 36 months if < 50 OR up to 60 months if >49	
G		U	R	Up to 6 months	
G		0	S	Maximum 15 months	As per District Settings
G		9	S	Maximum 15 months	As per District Settings
G		U	S	Maximum 15 months	As per District Settings

E = "Borderline changes in endocervical cells (HPV tested)"

New Result Code	Infection Code	Action Code	Repeat Months	
E	0	A	36 months if < 50 60 months if >49	As per District Setting
E	0	R	36 months if < 50 60 months if >49	
E	U	R	Maximum 6 months	
E	0	S	Maximum 12 months	As per District Setting
E	9	S	Maximum 12 months	As per District Setting
E	U	S	Maximum 12 months	As per District Setting

Any test result entered that fails the above validation rules will be rejected with the appropriate message. For example the screen below shows an E9R result/infection/action code combination being entered. 9 is an invalid infection code for an ER coded test result and is therefore rejected with the message "INFECT/RES conflict"

```
CY]Cytology Test
                           REJECT Qualifier[956 587 4588
                                                                    1
1. INFECT/RES conflict
                                                               page->
                                          DoB: 23.11.1979 Age: 32
Dr. T Asprilla Code: 000010
SMITH, Ms. Zoe Anne
                             Q Code:QT2
Extra Name:
3 Any Old Street, EXE
                                          Nat/Local District Code: L51/SM
EX0 0ZZ
Amend/Delete previous tests [N] Delete ALL Tests [NO]
                                   PNL Date:06.2012
                                                     Invited :06.2012
PNL Date:06.2012

Next Test due [01.06.2012] Recall Type [S]

Notif Date [19.06.2012] Recall Status [1] Patient Informed
National Code [1 ] BISHOP AUCKLAND, CO. DURHAM
                                                   Slide No. [12090875]
            [23.06.12 ] Sender National Code [
Test Date
                                                   ]
Result Notif [ ] Source [G] Sender [ ]
Result Code [E] Infection [9] Action Code [R] Rpt in [12] Months
Comment[
                                                          ]Complete?[ ]
                                                          ]Susp List[Y]
      Test 0 of 1 -----T-Flags-----
      Test Date Result Infection Action Code
                                                   Rpt Months | NB:
                                                    15 | FP69: FNR:
      01.06.2012 0
                                     S
                                                               | POS/DOUBT :N
                                                               AGE at NTD:
```

7.2 Mapping of HPV coded results to non HPV equivalents

If HPV coded tests require entering at a PCO who are not yet switched on for HPV testing the HPV coded test should be mapped to the following:

HPV Result	Infection	Action		Mapped Result	Infection	Action	Entered in CY record Comment line 3 – 1 st 4 or 6 characters
E	0	Α	Maps to	9		R	HPVN (36 or 60 repeat months value according to age)
E	0	R	Maps to	9		R	HPVN
E	U	R	Maps to	9		R	HPVU
E	0	S	Maps to	9		S	HPVN
E	9	S	Maps to	9		S	HPVP
E	U	S	Maps to	9		S	HPVU
G	0	Α	Maps to	0		Α	HPVN
G	0	R	Maps to	0		R	HPVN
G	U	R	Maps to	0		R	HPVU
G	0	S	Maps to	0		S	HPVN
G	9	S	Maps to	0		S	HPVP
G	U	S	Maps to	0		S	HPVU

7.3 Update

The CY screen update routines amended to update the test result details for the new result codes and to set the new recall date according to the rules outlined in 7.1 – validation rules.

7.4 Ceasing 'Due to Age'

The CY screen will use the new 'Ceasing due to Age' rules when assessing a woman's recall date following an 'A' coded action test result. These new rules will also be applied to the Laboratory Links system and the 'Deducted Transfer' software CINCD.

The new rules governing ceasing 'due to age' are explained in Section 11 of this document.

7.5 Changes to 'ABC' guidelines.

The CY screen will call the 'ABC guidelines' module ^CYABC for any test result entered that has an action code of "A". The 'ABC' module has been amended in line with the new rules governing a return to routine recall and is explained in Section 12 of this document.

8 AJ-CIN Changes (CINCD)

Minor changes have been made to the CINCD software to accommodate the 4 new result codes. The new automatic ceasing 'due to age ' rules and 'ABC3' return to routine recall will also be applied within CINCD processing. The print reports will display the new expansions for existing result codes and the expansion for the new result codes.

9 AJ-CP changes

Amendment made to AJ-CP letter print to report the new result codes. New ceasing 'due to age' letters will also be produced for women according to the result/infection/action code combination (see page 8 of the DD screen changes) that caused them to be ceased from recall.

We have also amended the setting of the 'infection' for result codes 1 and 2. Currently infection is set to 'Y'es if an infection code is present or 'N'o if none present. This infection marker is then used in combination with the Result and Action code to select the correct letter identity code to produce the result letter. As only infection codes 0, 9 or U are relevant now and the DD screen has been amended to show only infection not present screens for result codes 1 and 2, infection will always be set to 'N' from now on.

A change has also been made to disable the 'Letters sent from Laboratory flag' in line with withdrawal of LD screen 3 as all result letters should now be produced by the PCO.

10 AJ-RP changes

As per AJ-CP new recall letters/FNR notifications will be produced by AJ-RP for the new result/action code combinations as set up by district on the letter pages of the DD screen.

As detailed in AJ-CP above, we have also amended the setting of the 'infection' for result codes 1 and 2. Currently infection is set to 'Y'es if an infection code is present or 'N'o if none present. This infection marker is then used in combination with the Result and Action code to select the correct letter identity code to produce the RP notifications. As only infection codes 0, 9 or U are relevant now and the DD screen has been amended to show only infection not present screens for result codes 1 and 2, infection will always be set to 'N' from now on.

The production of Recall letters from AJ-RP has been disabled in line with the withdrawal of the screen 3 of LD.

11 Appendix A - Changes to ceasing 'due to age' rules

Amendments will be needed to introduce the new rules governing a woman's automatic ceasing 'due to age'.

NEW CEASING RULES

As a general rule, any woman whose test is coded 'A' for routine recall can be ceased automatically due to age unless there is an 'abnormal' result in any of her last three tests, including the final one. This is different from the previous rules where the woman had to have had a negative/routine recall test (i.e. one coded 2A or N-0-A).

When assessing if a woman may be ceased 'due to age' or not the following must be taken into account:

- Abnormal test is a test coded 3R, 3S, 4S, 5S, 6S, 7S, 8S, 9R or 9S
 Or B9R, B9S, E9S, G9S, M9R, M9S, N9R or N9S.
- If a woman has an abnormal test result in her history she may only be ceased due to age on the 3rd consecutive negative test result following the abnormal result. Private 'H' coded tests (0H, 1H & 2H) and Inadequate (Result code 1R or 1S) tests are discounted when calculating the number of negative test results following the abnormal test result.
- Women who have no abnormal test results

Ceasing due to age rules are as follows:

If most recent test has an action code of "A" the woman may be ceased as long as:

- 1. She will be aged 65 or more when her next test is due
- 2. She has no abnormal tests (result codes 3-9 or HPV positive infection (9) with results coded B, E, G, M or N) in her history.
- 3. She has abnormal test(s) but they were prior to her last 3 normal tests.

Normal tests are:

```
0A, 0H, 0R, 0S, 1H, 1R, 1S, 2A, 2R, 2S
B0A, B0R, B0S, BUR, BUS
E0A, E0R, E0S, EUR, EUS
G0A, G0R, G0S, GUR, GUS
M0A, M0R, M0S, MUR, MUS
N0A, N0R, N0S, NUR, NUS
```

Abnormal tests are:

```
3R, 3S, 4S, 5S, 6S, 7S, 8R, 8S, 9R or 9S
B9R, B9S, E9S, G9S
M9R, M9S, N9R or N9S
```

B9R, M9R & N9R are no longer used but historic tests exist so they need to be taken into account when assessing if a woman may be ceased 'due to age'.

Abnormal/Normal Results Table

HPV test result → Cytology result ↓	none (no HPV test)	0 (negative)	9 (positive)	U (no result)
0	normal	n/a	n/a	n/a
G	n/a	normal	abnormal	normal
1	normal	n/a	n/a	n/a
2	normal	n/a	n/a	n/a
N	n/a	normal	abnormal	normal
3	abnormal	n/a	n/a	n/a
M	n/a	normal	abnormal	normal
4	abnormal	abnormal	abnormal	abnormal
5	abnormal	abnormal	abnormal	abnormal
6	abnormal	abnormal	abnormal	abnormal
7	abnormal	abnormal	abnormal	abnormal
8	abnormal	n/a	n/a	n/a
В	n/a	normal	abnormal	normal
9	abnormal	n/a	n/a	n/a
E	n/a	normal	abnormal	normal

12 Appendix B - Changes to 'Return to Routine Recall' guidelines

A woman may be returned to routine recall following an abnormal test result according to the following rules:

We are awaiting confirmation from NHSCSP of the return to routine recall rules. We will add these rules to the document when confirmation is received.

13 Appendix C - Change Request 4636

Change Request Number: 4636

Summary:

Implement 4 new result codes in relation to the release of ABC3 in early 2012

Problem Description:

The system supports result codes 1-8 and M, B, N. New result codes will be required for two new cytology result categories (and two HPV-tested equivalents) when ABC3 is published early in 2012.

Suggested Solution:

Implement 4 new result codes as follows: 0 ?glandular neoplasia (non cervical); 9 borderline change in endocervical cells; G as 0 but HPV-tested; E as 9 but HPV-tested.

Potential Benefits:

Laboratories will be required to report screening tests according to the new categories from April 2012. NHAIS must be able to accept and process the new codes.